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Dutch experience with the fenestrated Anaconda endograft for short-neck infrarenal and juxtarenal abdominal aortic aneurysm repair

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Objective: In the past decennium, the management of short-neck infrarenal and juxtarenal aortic aneurysms with fenestrated endovascular aneurysm repair (FEVAR) has been shown to be successful, with good early and midterm results. Recently, a new fenestrated device, the fenestrated Anaconda (Vascutek, Renfrewshire, Scotland), was introduced. The aim of this study was to present the current Dutch experience with this device.

Methods: A prospectively held database of patients treated with the fenestrated Anaconda endograft was analyzed. Decision to treat was based on current international guidelines. Indications for FEVAR included an abdominal aortic aneurysm (AAA) with unsuitable neck anatomy for EVAR. Planning was performed on computed tomography angiography images using a three-dimensional workstation.

Results: Between May 2011 and September 2013, 25 patients were treated in eight institutions for juxtarenal ($n = 23$) and short-neck AAA ($n = 2$). Median AAA size was 61 mm (59–68.5 mm). All procedures except one were performed with bifurcated devices. A total of 56 fenestrations were incorporated, and 53 (94.6%) were successfully cannulated and stented. One patient died of bowel ischemia caused by occlusion of the superior mesenteric artery. On completion angiography, three type I endoleaks and seven type II endoleaks were observed. At 1 month of follow-up, all endoleaks had spontaneously resolved. Median follow-up was 11 months (range, 1–29 months). There were no aneurysm ruptures or aneurysm-related deaths and no reinterventions to date. Primary patency at 1 month of cannulated and stented target vessels was 96%.

Conclusions: Initial and short-term results of FEVAR using the fenestrated Anaconda endograft are promising, with acceptable technical success and short-term complication rates. Growing experience and long-term results are needed to support these findings. (*J Vasc Surg* 2014;60:301–7.)

In the past 2 decades, endovascular aneurysm repair (EVAR) has evolved rapidly and has proven to be a good alternative to open repair in the treatment of infrarenal abdominal aortic aneurysms (AAAs). Advantages of EVAR include reduced periprocedural mortality, reduced postoperative complications, less blood transfusion requirement, and shorter hospital stay.^{1–4} A variety of standard commercial devices are available for infrarenal EVAR. Standard endografts are insufficient in more complex anatomy

lacking an adequate sealing zone in the infrarenal aorta (short neck length <15 mm, angulation >60°, a reversed conical neck, or aneurysm involvement of important aortic side-branch vessels).

Fenestrated and branched endografts have been developed for the treatment of these complex aneurysms. The use of fenestrated endografts was first introduced in 1996, and the subsequent evolution in devices and delivery systems has been enormous.⁵ In the past decennium, the management of short-neck infrarenal, juxtarenal, and suprarenal aortic aneurysms with fenestrated endovascular aneurysm repair (FEVAR) has been shown to be successful, with good early and midterm results.^{6–8} Most of the accumulated experience has involved the Zenith (Cook Medical Australia, Brisbane, Queensland, Australia) custom-made fenestrated endograft.

Recently, the new Fenestrated Anaconda Endograft (Vascutek, Renfrewshire, Scotland) was introduced for the treatment of juxtarenal and infrarenal AAAs with a short neck. Potential advantages of the endograft include the ability to reposition the body with a controlled deployment system, the ability to position the superior mesenteric (SMA) or celiac artery (CA) in an anterior augmented scallop, the ability to cannulate target vessels using axillary access, and the lack of stent material compromising the position of the fenestrations. The initial experiences with this new device were published in 2011 by Bungay et al.⁹

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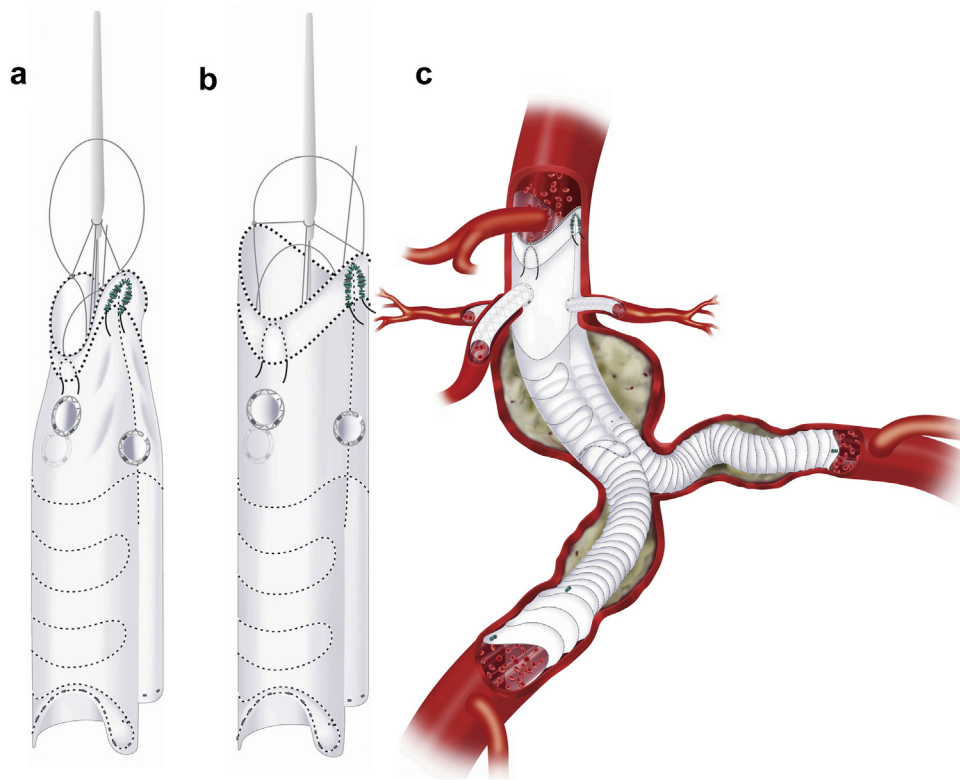


Fig 1. Illustrations of the fenestrated Anaconda show (a) the endograft with the top stents collapsed, (b) the endograft after deployment, and (c) the endograft in situ. In this case, a three-fenestration device with a valley for the celiac artery (CA) was used. (Figure provided by Vascutek, Renfrewshire, Scotland.)

The aim of this study was to present the first Dutch experience with the fenestrated Anaconda endograft.

METHODS

Design of the study. A prospectively held database was retrospectively analyzed. Research collaborators at the respective hospitals prospectively collected the data, which were entered into a centrally kept database. All patients underwent preoperative assessment using multislice-detector computed tomography angiography (CTA). The decision to treat was according to current international guidelines.^{10,11} Indications for FEVAR included an AAA with unsuitable neck anatomy for conventional EVAR (aortic neck length <15 mm, neck angulation >60°, conical neck). Planning was performed from CTA images and multiplanar reconstructions on a three-dimensional (3D) workstation. The procedures took place in a hybrid suite equipped for interventional radiology and open surgical procedures or in a surgical theater using a recent-generation mobile C-arm.

Follow-up consisted of CTA at 1 month and 1 year, and CTA scanning every other year thereafter. Given the data were anonymous and analysis performed retrospectively, the study was exempted from Institutional Review Board approval.

Description of the fenestrated Anaconda endograft.

The fenestrated Anaconda endograft is a new customizable device for individual patient use and is based on the Anaconda AAA endograft system (Conformité Européenne approved).¹² The device is trimodular and consists of a dual proximal ring stent with two or four fixation hooks (depending of the configuration of the fenestrations), an unsupported graft body that facilitates the nitinol-reinforced fenestrations, and a distal ringed stent. A range of endograft configurations is currently available, allowing for one up to four fenestrations. Also, the addition of an augmented valley (comparable to a scallop) and a bifurcated or a tube design add further possibilities to treat AAAs with a various range of anatomy (Fig 1). The instructions for use advise oversizing the main device by 10% to 20%. The outer diameter of the main device introducer is 20F or 23F, depending on the size. Construction time for the device is ~6 weeks.

The fenestrated Anaconda has several special features that are new. It can be repositioned after full deployment, allowing for accurate deployment and easy repositioning of the endograft body and its fenestrations. The fenestrations are placed in the unsupported region, in this way maximizing the area available and potentially allowing for easier alignment and subsequent cannulation of target vessels. The lack of columnar strength combined with a ringed

distal design might also allow for treatment of more angulated and stenotic anatomy.

Preoperatively, a 3D model of each patient's aorta was made and a test run performed using an exact copy of the endograft that was planned to be implanted. This allowed for ex vivo visualization of the endograft and fenestration position and also for radiographically controlled cannulation of fenestrations with wires and catheters.

Stent implantation. Bilateral open femoral access was obtained. All patients received 5000 U of heparin before femoral artery cannulation, with additional boluses of heparin added intraoperatively depending on the length of the procedure. After introduction and deployment of the fenestrated main body, the fenestrations and target vessels were cannulated, guided by the four radiopaque markers at each fenestration and by the radiopaque saddle-shaped top stents (Fig 1). At this point, angiography was performed to confirm the position. If not satisfactory, the control and release wires could be used to collapse the top ring stent and the device repositioned to achieve a more satisfactory position. Once the graft was in place, the target vessels were provided with covered stents using standard endovascular techniques, which were flared with a 12-mm × 20-mm balloon. Finally, the limb extensions were placed, and a completion angiogram was performed.

Definitions. Juxtarenal was defined as an aneurysm that abutted the renal arteries but did not involve the renal arteries (no normal aorta between upper extent of aneurysm and renal arteries). Short neck was defined as an aneurysm with a normal portion of the aorta between the upper extent of the aneurysm and lowest renal artery and with a neck length <15 mm.

Technical success was defined as the successful introduction and deployment of the device in the absence of surgical conversion or death, type I or III endoleaks, or graft limb obstruction ≤24 hours postoperatively.

Clinical success (initial and short-term) was defined as successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, type I or III endoleak, graft infection or thrombosis, aneurysm expansion (diameter >5 mm or volume >5%), aneurysm rupture, or conversion to open repair. Graft dilatation of ≥20% by diameter, graft migration, or a failure of device integrity were classified as a clinical failure.¹³

Statistics. Data analysis was performed using SPSS 20.0 software (IBM Corp, Armonk, NY). Continuous variables are described as mean ± standard deviation or as median and interquartile range (IQR) in case of skewed data. Differences between continuous variables were tested using a paired Student *t*-test. Two-sided *P* values of <.05 were considered significant.

RESULTS

Between May 2011 and September 2013, 25 procedures were performed at eight institutions in The Netherlands. Patient demographics are reported in Table I. Mean aneurysm size was 64 ± 8.8 mm. AAAs were juxtarenal in 23

Table I. Demographic and operative characteristics

Variable	Value
Gender, No. (%)	
Male	22 (88)
Female	3 (12)
Age, mean ± SD, years	73 ± 7.1
Comorbidities, ^a No. (%)	
Diabetes mellitus	3 (12)
Hypertension	15 (60)
Hypercholesterolemia	9 (36)
Current smoker	9 (36)
Cardiac disease	18 (72)
Pulmonary disease	3 (12)
Renal disease	8 (32)
ASA score, No. (%)	
2	12 (48)
3	12 (48)
4	1 (4)
Aneurysm anatomy, No. (%)	
Juxtarenal	23 (92)
Short neck	2 (8)
AAA diameter, median (IQR), mm	61 (55-88)
Number of fenestrations, ^b No. (%)	
1	3 (12)
2	15 (60)
3	5 (20)
4	2 (8)

AAA, Abdominal aortic aneurysm; ASA, American Society of Anesthesiologists (ASA) Physical Status Classification; IQR, interquartile range; SD, standard deviation.

^aDefinitions: Diabetes includes patients being treated with oral antidiabetic medication or insulin. Hypertension includes diastolic blood pressure >90 mm Hg uncontrolled or controlled by medication. Hypercholesterolemia includes uncontrolled or controlled by medication. Cardiac disease includes congestive heart failure, coronary artery disease, and previous myocardial infarction. Pulmonary disease includes chronic obstructive pulmonary disease Global Initiative for Chronic Obstructive Lung Disease ≥2. Renal disease is indicated by an estimated glomerular filtration rate <60 mL/min/1.73 m².¹¹

^bFor detailed stent configuration, see the Methods section.

patients (92%), and the remaining two had a short neck (3 and 6 mm). Eleven patients were deemed suitable for both open surgical repair and EVAR.

Three endografts had one fenestration (12%), 15 endografts (60%) had two fenestrations, of which 14 incorporated both renal arteries, and one endograft incorporated a renal artery and the SMA. Five endografts (20%) had three fenestrations incorporating the left and right renal artery and the SMA. Two endografts had four fenestrations incorporating both renal arteries, the SMA and the CA. Median aortic diameter at the level of the proximal landing zone was 26 mm (IQR, 24.5-27.3 mm). All except one were bifurcated devices. The patient treated with an aortouni-iliac device had previously been treated with an infrarenal device, which was then complicated by graft migration due to neck dilatation and occlusion of the left limb. Devices were oversized by a median 17.3% (IQR, 16.7%-23.1%).

A total of 56 fenestrations were incorporated, and of these, 53 (94.6 %) were successfully cannulated and stented. Full procedural details are reported in Table II.

Table II. Procedural details and follow-up

Details	Value ^a
Procedures performed per institution, No.	3 (1-5)
Fluoroscopy time, minutes	67 (53-107)
Operative time, minutes	240 (190-356)
Contrast dose, mL	194 (103-320)
Technical success	21 (84)
Clinical success	23 (92)
Graft repositioned	
Yes	16 (64)
No	5 (20)
Unknown	4 (16)
Early complications (<30 days)	
Compartment syndrome left lower leg	1 (4)
Rupture of common iliac artery	1 (4)
Occluded SMA	1 (4)
Perforation of a renal artery	2 (8)
Cutaneous bleeding	1 (4)
Type I endoleak ^b	3 (12)
Type II endoleak ^b	7 (28)
Late complications (>30 days)	
Hemorrhagic CVA	1 (4)
Renal function	
eGFR, mL/min/1.73 m ²	
Preoperative	61 ± 16
Postoperative at 1 month	56 ± 19 ^c
Creatinine, μmol/L	
Preoperative	103 ± 30
Postoperative	115 ± 56 ^d

CVA, Cerebrovascular accident; eGFR, estimated glomerular filtration rate; IQR, interquartile range; SMA, superior mesenteric artery.

^aContinuous data are shown as the median (IQR) or mean ± standard deviation, and categorical data are shown as number (%).

^bSpontaneously resolved at the 1 month follow-up, no reintervention to date.

^c*P* = .07.

^d*P* = .249.

Axillary artery access was required in four patients (16%) due to steep downward angulated target vessels. In 16 patients (64%), the endograft was repositioned. One ancillary left renal artery ruptured during covered stent expansion, which was subsequently treated with an occluding Amplatzer plug (St. Jude Medical, St. Paul, Minn). In this case, an ancillary renal artery was cannulated instead of the main renal artery for which the covered stent was measured. This also led to occlusion of the main renal artery, as seen on follow-up CTA, although there was contrast uptake by the kidney and renal function did not suffer.

Cannulation of the CA through the fenestration was not successful in one patient. Completion angiography showed retrograde filling of the CA through collateral circulation, without signs of an endoleak. The situation was accepted, and these findings were confirmed on the 1-month follow-up CTA.

One SMA occluded ≤24 hours postoperatively because of inadequate alignment of the SMA fenestration and the SMA origin. During the procedure, the marker of the guiding sheath seemed appropriately located in the valley of the main body and origin of the SMA in two plains (angiography). In retrospect, however, the operators concluded that the main body was not positioned as

planned, but rotated by 15°. A CTA the day after surgery showed that the SMA stent was positioned between the aortic wall and the main body of the endograft, which led to occlusion of the SMA origin (Fig 2). The SMA was supplied with blood through the gastroduodenal artery. Trashing of thrombus, mainly to the kidneys and visceral arteries, also occurred during the same procedure. The endograft was repositioned once during the case, and the right common iliac artery ruptured during deployment and was subsequently overstented using the (covered) right limb extension. These complications led to renal failure and bowel ischemia, for which a laparotomy and a left extended hemicolectomy were performed the day after surgery. Subsequently, the patient developed myocardial ischemia and multiorgan failure and died. One patient developed a compartment syndrome of the left lower leg postoperatively, for which a fasciotomy was performed.

All renal arteries were stented using the Advanta V12 covered stent (Atrium, Hudson, NH). In two fenestrations, a bare-metal stent was used instead of a covered stent (one for the SMA and one for the CA).

Completion angiography showed three type I endoleaks, which spontaneously resolved on the 1-month follow-up CTA (Fig 3), seven type II endoleaks, and no type III endoleaks. At the 1-month follow-up, there were no endoleaks. No aneurysm growth was observed on 1-month follow-up CTA.

Median follow-up was 11 months (IQR, 1-29 months). There were no aneurysm ruptures. One patient died of bowel ischemia as a result of an occluded SMA. Another patient died of hemorrhagic stroke 3 months postoperatively, which was attributed to the use of antiplatelet agents. There were no reinterventions to date.

DISCUSSION

This study shows that the fenestrated Anaconda endograft can be used safely and effectively and offers an alternative for the treatment of short-necked infrarenal and juxtarenal AAAs. In this relatively small series, an acceptable technical success rate was achieved. The occurrence of endoleaks in this series grossly corresponded to the prevalence reported in previous studies.¹⁴ Type II endoleaks are known to often resolve spontaneously. The type I endoleaks seen on completion angiography all disappeared as well. Further research is necessary, but the fenestrated Anaconda seems to do well, even in case of a mild type I proximal endoleak. One reason might be that the double saddle-shaped nitinol top ring needs some time to fully expand and adapt to the specific neck anatomy.

The fenestrated Anaconda has the possible advantage of being repositionable. After partial or full deployment, the saddle-shaped top part of the device can be collapsed, allowing for rotation and craniocaudal repositioning. In earlier reports on the use of the Anaconda for infrarenal AAA repair, the endograft was repositioned in 10% to 38% of the cases to achieve a more satisfactory position.¹⁵⁻¹⁷ Accurate placement of the device is especially important in FEVAR, where alignment between the



Fig 2. Inadequate placement of the superior mesenteric artery (SMA) stent in the augmented valley of the main body led to an occlusion in one patient. During the procedure, the marker of the guiding sheath seemed to be located in the valley of the main body in two plains (angiography). In retrospect, however, the operators believe the main body itself was not positioned in the right angle. The figure shows (a) the angiogram with cannulation of the SMA with a guiding sheath, (b) angiogram in the left anterior oblique position with a guidewire in the SMA, and (c) computed tomography angiography (CTA) showing the stent positioned between the aortic wall and the main body of the endograft.

fenestration and the target vessel origin is the key for successful target vessel cannulation and stenting. Combined with the unsupported main body, the possibility to reposition may allow for more versatility when cannulating the target vessels. In four patients in this series, there was no record whether the endograft was repositioned. In 16 patients (64%), the endograft was repositioned, suggesting this is a much-used feature. However, it poses the question whether this is due to design features that predispose to inaccurate primary placement or simply having the option to reposition and therefore doing so.

Another feature is the unsupported midportion of the graft, allowing for more versatility and also allowing fenestrations to be placed close to each other. This may be a benefit in planning and customizing. However, during ex vivo deployment and repositioning, the operators observed that an intussusception could occur where the top supported portion of the graft slides into the unsupported body. Partial deployment up to the level of the fenestrations, followed by cannulation of the target vessels from an axillary approach and eventually full deployment of the device, could overcome this problem when anticipated preoperatively.

In addition, the device has been adapted with additional supporting suture lines. Also, the relative lack of support in the area of the fenestrations can lead to fenestration-to-target vessel mismatch because of an

increased range of motion of the unsupported fabric. This was observed in one of the patients, in whom an ancillary renal artery was cannulated instead of the main renal artery.

Another disadvantage of the possibility to reposition the endograft is that embolization of thrombotic material lining the aneurysm can occur. This happened in one patient and led to kidney failure and at least added to ischemia of the large bowel and, ultimately, to the patient's death. In this specific case, the endograft was repositioned once during the procedure. Nonetheless, the occurrence of thromboembolic events warrants a careful approach with regard to repositioning the device.

Most of the experience using fenestrated endografts, in The Netherlands and worldwide, is with the Zenith-based device (Cook Inc, Bloomington, Ind). As with all fenestrated devices, the fenestrated Anaconda is customized to fit the specific patient's anatomy. This calls for careful planning and collaboration with the manufacturer. In some cases, measurements were adjusted as a result of the test on the 3D model of the patient's aorta.

All procedures were performed by a team consisting of a vascular surgeon, with or without an interventional radiologist. Personnel in all institutions were trained and made familiar with FEVAR procedures. A relatively long median operative time and high contrast dose were observed in this series. Several factors might have contributed to this. As with any new device one would expect a learning curve.

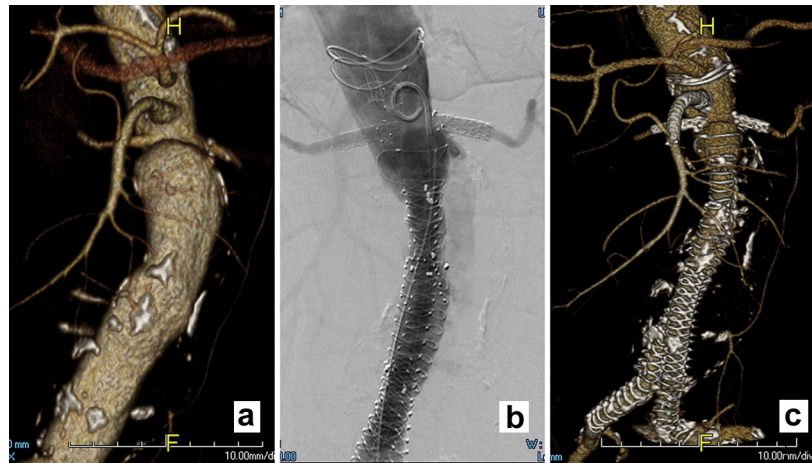


Fig 3. **a**, A preoperative computed tomography angiography (CTA) three-dimensional (3D) reconstruction shows a short-necked aneurysm. **b**, A completion angiogram shows patent target vessels and a small type I endoleak. **c**, A 3D reconstruction of the 1-month follow-up CTA shows the endograft in situ. Review of early-phase and late-phase images showed that the endoleak had spontaneously resolved.

This was especially true for two institutions starting FEVAR with this device.

Furthermore, compared with other devices, the fenestrated Anaconda might allow for treatment of more complex anatomy due to specific design features. In a number of patients, the Cook fenestrated device was deemed unfavorable because of the proximity of target vessels, which could have resulted in a selection bias.

The operative time and fluoroscopy time were comparable to those in initial series reporting on the use of other endografts. Contrast dose was slightly higher in this series compared with early experiences with the Cook device (194 vs 170 mL).^{18,19} This might be due to the option to reposition the endograft, in which case angiography is often performed to verify the adequacy of the new position. However, compared with the recently introduced Ventana fenestrated device (Endologix, Inc, Irvine, Calif), the contrast dose is slightly less (194 vs 254 mL).²⁰

There have been no reinterventions to date during follow-up. This series achieved a satisfying technical and clinical success rate. Further studies are needed to evaluate long-term outcome, applicability, and actual differences between available devices.

A limitation of the endograft is the maximum diameter of 34 mm for the main device, which might pose a problem when treating an aneurysm with a large diameter proximal landing zone. The fenestrated Anaconda instructions for use are based on the standard Anaconda platform and dictate a 10% to 20% oversize for optimal sealing. Long-term results will clarify whether this is true for juxtarenal aneurysms, specifically in terms of late occurrence of proximal type I endoleaks or migration, or both.

Limitations of the study include the relative small number of patients and the short-term follow-up, which makes

it difficult to draw conclusions about patient outcome other than clinical success. Especially, the low rate of reintervention and occurrence of endoleaks should be interpreted with caution. No aneurysm growth was observed, but this could be expected, and ongoing surveillance and follow-up are needed to confirm this.

CONCLUSIONS

The initial and short-term results of FEVAR using the fenestrated Anaconda endograft are promising, with satisfying technical success and short-term complication rates. Growing experience, midterm results, and long-term results are needed to support these findings.

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AUTHOR CONTRIBUTIONS

Conception and design: MD, IT, RM, CZ

Analysis and interpretation: MD, IT, CZ

Data collection: MD

Writing the article: MD, CZ

Critical revision of the article: IT, RM, MP, JB, GS, JL

Final approval of the article: MD, IT, RM, MP, JB, GS, JL, CZ

Statistical analysis: MD

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